Individual Safety Report

3460714-7-00-01

FOR DIA... :C'D

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

FEB 22 2000

CDR

McNeil Consumer Healthcare

McNeil Consumer Healthcare
Ft Washington, PA 19034-2299

Page ___ of ___

Approved by FDA on 11/15/93

MfR report #

UF/Diet report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	Weight
[redacted] In confidence	or 41 yrs Date of birth:	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (X) death 11/25/98 (mo/day/yr)
- ( ) life-threatening
- (X) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- (X) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event: 11/12/98 (mo/day/yr)

4. Date of this report: 02/11/00 (mo/day/yr)

5. Describe event or problem

Lit report (Artificial Organs 1999;23(7):631) of a clinical experience associated w/Phase I clinical safety evaluation of Bioartificial Liver Support System (BLSS) in tx of pt's presenting w/encephalopathy deteriorating beyond Parson's grade 2 from fulminant or acute-on-chronic liver failure. According to abstract, a 41 yo F presented w/worsening ENCEPHALOPATHY, evidence of acute (acetaminophen-induced) liver injury (LIVER DAMAGE), hypertension & systemic lupus. Pt rec'd 2 txs w/BLSS. Pt's APTT remained above 200s (COAGUL TIME INC). Pt reportedly tolerated tx well, regained nl mental status after txs & was extubated 6 days post-tx. Pt died (DEATH) 12 days post presentation from SEPSIS. Addl info rec'd 2/11/00: Med recs from physician indicates that pt was adm to liver tx ICU on 11/12/98 w/FHF very likely due to TYLENOL® toxicity. Pt presented w/grade 2 encephalopathy which became worse. Pt tx w/bio-artificial liver. Pt developed multi-system organ failure w/renal failure (KIDNEY FAILURE), GI bleeding (GI HEMORRHAGE), & over (See Sect C10)

6. Relevant tests/laboratory data, including dates

11/12/98: WBC=9.3(16%bands/55%polys),Plt=53,000,PT=27.9,PTT=PTT=30.5,BUN=64,BUN=64,Cr=1.8,Cl=109,TCO2=15,Tbili=20.5,Dbili=17.6,AP=257 GGT=977,SGPT=9375,SGOT=7590,LDH=9650; 11/13: transjugular liver biopsy subsequently (See Sect B7)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

SLE,lupus nephritis,s/p cholecystectomy,meningitis,cervical CA,s/p hysterectomy & BSO (Sect B6 cont) showed 60% necrosis; 11/14: HR=96-110, CT scan head was nl; 11/17: WBC=11.1, bili=16.1; 11/19: Endoscopy showed esophagitis; 11/21/98: T=37.1C, HR=120, BP=180/99; 11/22: bili=26.2;11/23: WBC=0.6; 11/24: plt=5000 PT=29.7, PTT=82.7; 11/25: bili=16.7

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 unspecified TYLENOL® product

#2

2. Dose, frequency & route used

#1 unknown dose, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 unknown dates or duration

#2

4. Diagnosis for use (indication)

#1 unknown

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 unknown

#2

7. Exp. date (if known)

#1 unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

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10. Concomitant medical products and therapy dates (exclude treatment of event)

steroids, CYTOXAN® (Sect B5 cont) next 1-2 weeks septic shock (SEPSIS). Pt's blood cx was (+) for E.Faecalis on 11/13/98 & (+) for Pseudomonas on 11/22/98. Pt had cardiac arrest (HEART ARREST) on 11/23/98 & died (DEATH) on 11/25/98

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

FEB 22 2000

2. Phone number: 215-273-7303

3. Report source (check all that apply)

- ( ) foreign
- ( ) study
- (X) literature
- ( ) consumer
- (X) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 02/11/00

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- ( ) Initial (X) follow-up # 1

8. Adverse event term(s)

ENCEPHALOPATHY
LIVER DAMAGE
COAGUL TIME INC
KIDNEY FAILURE
HEMORRHAGE GI
SEPSIS
HEART ARREST
DEATH

9. Mfr. report number: 1242145A

E. Initial reporter

1. Name, address & phone #

J.F. Patzer II
Starzl Transplantation Institute
W1544 Biomedical Science Tower
Pittsburgh, PA 15213

FEB 23 2000

2. Health professional? (X) Yes ( ) No

3. Occupation

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

FDA

Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.